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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,708	04/15/2004	James A. Shayman	3646.1001-013	7244

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EXAMINER

COPPINS, JANET L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,708

Applicant(s)

SHAYMAN, JAMES A.

Examiner

Janet L. Coppins

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 18-23 and 26-31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-17, 24 and 25 is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☒ Claim(s) 2, 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claims 1-31 pending in the instant application.

Information Disclosure Statements

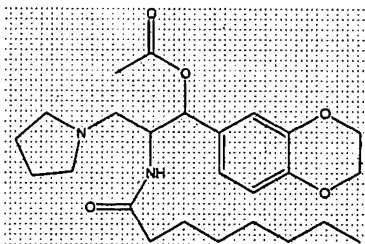
1. Receipt is acknowledged of Applicants' Informational Disclosure Statements, filed April 15, 2004 February 2, 2005, have been considered by the Examiner. Please refer to Applicants' copies of the PTO-1449 forms submitted herewith.

Preliminary Amendment

2. Receipt is acknowledged of Applicants' Preliminary Amendment, submitted August 18, 2005, which has been reviewed by the Examiner and entered of record. Accordingly, claims 1, 5, 12, and 24 have been amended.

Election/Restrictions

3. Applicants' election of Group I, claims 1-5, 12-17, 24, and 25, drawn to compounds, and specific compound of:



in the response filed August 18, 2005, is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 6-11, 18-23, and 26-31, of non-elected Groups II-VII, are hereby withdrawn from consideration as drawn to non-elected subject matter.

Art Unit: 1626

4. Regarding the status of claim 18, the Examiner had inadvertently included the claim in both Group I, drawn to compounds, and Group II, drawn to methods. Because claim 18 is a method claim, the Examiner had intended it to belong in Group II, and apologizes for any inconvenience.

Status of the claims

5. Claims 1-31 are pending in the application. Claims 6-11, 18-23, and 26-31, as previously stated, are currently withdrawn from further consideration as being drawn to non-elected inventions. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one group, would not necessarily render obvious another group.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1626

8. Claims 1 and 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Inokuchi et al, JP 10324671 as well as the CAPLUS abstract in English.

Applicants are claiming the following product:

The claims are directed to amino ceramide compounds according to the formula of claim 1.

Determining the scope and content of the prior art

Inokuchi et al disclose similar amino ceramide analogs according to formula (I) of page 2, for the treatment of nerve diseases.

Ascertaining the difference between the prior art and the claims

The difference between the prior art and the instant claims is that Inokuchi et al teach a decanamide substituent (which corresponds to Applicants' "NH-C(=O)-R₂" moiety), while Applicants only teach aliphatic chains having 6, 7, or 8 carbons.

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art to employ the instant claimed amino ceramide-derivatives since the prior art reference discloses amino ceramide-analogs that have the same general structure and are used for treating diseases associated with altered GSL levels. To those skilled in chemical art, an aliphatic chain with nine, ten, etc carbons is not such an advance over an aliphatic chain with six, seven, or eight carbon atoms, because chemists knowing properties of one amino ceramide analog would in general know what to expect in a homologous amino ceramide analog differing only in the number of alkyl carbon atoms. Please refer to compounds RN 219117-35-8, 219117-34-7, 219117-33-6, and 219117-31-4, for example. The motivation to use the claimed

Art Unit: 1626

compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. ceramide analogs for treating diseases associated with GSL levels). The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to use the compounds taught in the reference with a decanamide or nonanamide substituent, as ceramide analogs, with the expectation of altering GSL and ceramide levels in a patient in need thereof. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Objections

9. Claims 2, 4, and 5 are objected to as being dependent on rejected base claims.

Conclusion

10. In conclusion, claims 1-31 are pending. Claims 6-11, 18-23, and 26-31 are currently withdrawn from consideration as being drawn to non-elected inventions. Claims 1 and 3 stand rejected, and claims 2, 4, and 5 are objected to. Claims 12-17, and 22-25 appear to be allowable over the prior art.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
September 2, 2005

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

for Kamal Saeed
Joseph K. McKane
SPE, Art Unit 1626